K071097

OCT 10 2007

Premarket Notification 510(k) Summary
As required by section 807.92
Navigator Applications Suite

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare Finland OY
C/O Datex-Ohmeda
PO Box 7550
Madison, WI 53707 USA
Tel: 608-221-1551
Fax: 608-223-2496

NAME OF CONTACT:

Ms. Adrienne Lenz

DATE:

April 13, 2007

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Navigator Applications Suite

COMMON NAME:

Navigator Applications Suite

CLASSIFICATION NAME:

BSZ, Accessory to gas machine for anesthesia or analgesia

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Navigator Applications Suite is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Anesthesia Monitor (K030812) with L-ANE03 and L-ANE03A software and Datex-Ohmeda Network and iCentral (K052972).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Navigator Applications Suite is a product that integrates information from a anesthesia delivery system, intravenous drug infusion pumps, and patient monitor. The three main functions of the Navigator are:

- Navigator Therapy: Visualization of the modeled effect of the anesthesia drugs on the patient displayed on a point-of-care Navigator computer. The visualization is based on pharmacokinetic and pharmacodynamic (PK/PD) models and multi-drug models for propofol and four analgesic drugs. Navigator also supports automatic data capture from supported intravenous drug infusion pumps to minimize manual data entry
- Navigator Protocol: Framework to enable access to facility-selected care protocols at the point of care.
- Navigator Device: Electronic and interactive instructions for users to address technical issues with anesthesia delivery systems.

INTENDED USE as required by 807.92(a)(5)

Navigator Applications Suite (Navigator) is a software package that includes Navigator Therapy, Navigator Protocol and Navigator Device. Navigator software is loaded into a medical grade PC physically mounted to the Anesthesia Delivery System and receives data from supported Anesthesia Delivery Systems, Anesthesia Patient Monitors and Intravenous Drug Infusion Pumps.

Navigator Therapy displays pharmacokinetic, pharmacodynamic (PK/PD) and synergistic PD modeling information. Navigator Therapy provides the heath care provider with information about the modeled effect of supported anesthesia pharmaceuticals delivered to the patient.

Models only apply to the following patient populations:

Age:	18 - 90 years old
Weight:	40Kg - 140 Kg
Height	150cm - 190cm

Calculated drug concentrations and effects are based on published models, and do not represent actual measurements from a patient. Drug models are calculated and displayed assuming a healthy patient.

Navigator Protocol allows facilities to load electronic versions of care protocols. This feature can be configured with selected patient monitoring parameters available for viewing in conjunction with the care protocol.

Navigator Device is a troubleshooting aid with access to certain Anesthesia Delivery System alarm information.

The system is designed for facility use and should only be used under the orders of a clinician.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

With respect to Navigator Therapy, the Navigator is similar to the Datex-Ohmeda S/5 Anesthesia Monitor (K030812). The S/5 Monitor measures the anesthetic agent level being delivered and applies a mathematical model and displays the estimated Minimum Alveolar Concentration (MAC), which is an estimate of the anesthetic effect on the patient. Similar to the PK/PD models in Navigator, the MAC models implemented in the S/5 Monitor were first published in peer-reviewed journal articles. Both devices provide clinicians with information about the anesthesia pharmaceuticals delivered to the patient.

The devices differ in their general construction. The Navigator Applications Suite is a medical software program loaded onto a medical grade PC that is physically mounted to an anesthesia machine whereas the S/5 Anesthesia Monitor includes integrated modules containing both hardware and software. The Navigator Applications Suite does not have direct contact with the patient. The S/5 Anesthesia Monitor, depending on module configuration, can have several points of direct patient contact.

The S/5 Anesthesia Monitor displays MAC of anesthetic agents. The Navigator Applications Suite differs in that its pharmacokinetic models display effect site concentration (Ce), taking into account the temporal delay between changes in alveolar concentration and subsequent changes in the concentration at the site of drug effect. The Navigator Applications Suite also differs in that intravenous drugs can be displayed as well as inhaled agents. The Navigator Applications Suite also can display pharmacodynamic models for intravenous drugs, including synergies between some drugs.

The Navigator Applications Suite communicates with other devices using communication methods similar to the Datex-Ohmeda S/5 Network and Central (iCentral), K052972.

The protocol and device features of the Navigator Applications Suite take information that is currently available to the hospital in paper form and displays them electronically at the point of care.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2007

GE Healthcare Finland OY
C/O Ms. Adrienne Lenz
Senior Regulatory Affairs Specialist
Datex-Ohmeda, Incorporated
Post Office Box 7550
Madison, Wisconsin 53707

Re: K071097
Trade/Device Name: Navigator Applications suite
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: September 21, 2007
Received: September 24, 2007

Dear Ms. Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: Navigator Applications Suite

Indications For Use:

Navigator Applications Suite (Navigator) is a software package that includes Navigator Therapy, Navigator Protocol and Navigator Device. Navigator software is loaded into a medical grade PC physically mounted to the Anesthesia Delivery System and receives data from supported Anesthesia Delivery Systems, Anesthesia Patient Monitors and Intravenous Drug Infusion Pumps.

Navigator Therapy displays pharmacokinetic, pharmacodynamic (PK/PD) and synergistic PD modeling information. Navigator Therapy provides the heath care provider with information about the modeled effect of supported anesthesia pharmaceuticals delivered to the patient.

Models only apply to the following patient populations:

Age:	18 – 90 years old
Weight:	40Kg – 140 Kg
Height	150cm – 190cm

Calculated drug concentrations and effects are based on published models, and do not represent actual measurements from a patient. Drug models are calculated and displayed assuming a healthy patient.

Navigator Protocol allows facilities to load electronic versions of care protocols. This feature can be configured with selected patient monitoring parameters available for viewing in conjunction with the care protocol.

Navigator Device is a troubleshooting aid with access to certain Anesthesia Delivery System alarm information.

The system is designed for facility use and should only be used under the orders of a clinician.

Prescription Use _XXX_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071097